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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,108

09/25/2003

Homme W. Hellinga

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7590

06/28/2006

JENKINS, WILSON, TAYLOR & HUNT, P. A.  
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SUITE 1200  
DURHAM, NC 27707

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/672,108	<b>Applicant(s)</b> HELLINGA ET AL.	
	<b>Examiner</b> Ja-Na Hines	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 32-41 and 57 is/are pending in the application.  
     4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32 and 39-41 is/are rejected.
- 7) ☒ Claim(s) 33-38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Amendment Entry***

1. The amendment of March 20, 2006 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-31 and 42-56 have been cancelled. Claim 57 has been newly added. Claims 32-41 are drawn only to SEQ ID NO:5 and 6 are under consideration in this office action.

***Election/Restrictions***

2. Newly submitted claim 57 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The sequences are patentably distinct and an unduly burdensome search would result if claim 57 were included in the election. In the instant case these sequences are unrelated and distinct and the search of the polypeptides are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. As such, it would be burdensome to search all the sequences together. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 57 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Specification***

3. The amendment filed March 20, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Support related to SEQ ID NO:30 at positions 44 and 45. Applicants state that the GBI polypeptide wherein threonine 44 and tyrosine 45 have each been replaced by any of the other 19 amino acids, can be found at page 20, lines 1-7. However the page 20, lines 1-7 states that:

“An alternative embodiment of a GBI domain polypeptide of the present invention comprises mutations at a threonine 35 residue and at a tyrosine 45 residue of a native GBI domain polypeptide. The mutation comprises a substitution of the threonine 35 residue and tyrosine 45 residues with any of the other 19 amino acids, as it is contemplated by the present inventors that any such substitution substantially abolishes Fc binding activity while maintaining Fab binding activity.”

Applicant is required to cancel the new matter in the reply to this Office Action.

***Withdrawal of Rejections***

4. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The written description rejection of claims 32 and 35-41 under 35 U.S.C. 112, first paragraph;
- b) The rejection of claims 32 and 39-41 under 35 U.S.C. 112, second paragraph;
- c) The judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-33; and
- d) The rejection of claims 32 and 35-40 under 35 U.S.C. 102(a) as being anticipated by Sloan et al., (Protein Engineering, 1998).

### ***Response to Arguments***

5. Applicant's arguments filed March 20, 200 have been fully considered but they are not persuasive.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 32 and 39-41 under 35 U.S.C. 102(b) as being anticipated by Fahnestock et al., (US Patent 4,977,247) is maintained for reasons already of record.

The rejection was on the grounds that Fahnestock et al., clearly teach an isolated nucleic acid molecule encoding the B1 domain of Streptococcal protein G (GB1) polypeptide which binds a Fab fragment of an Immunoglobulin G (IgG) but does not

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bind a Fc fragment of IgG which is comprised within a recombinant expression vector and a host cell.

Applicants' assert that because Fahnestock et al., teach some polypeptide fragments that maintain binding affinity for Fab and Fc fragments, Fahnestock et al., do not teach the instant invention. Applicants' also urge that Fahenstock teaches away from nucleic acid molecule encoding the B1 domain of Streptococcal protein G (GB1) polypeptide which binds a Fab fragment of an Immunoglobulin G (IgG) but does not bind a Fc fragment of IgG, because of that teaching.

However it is the examiner's position that the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998). Therefore applicant's argument is not persuasive especially when considering the variants are used to isolate the Fc and Fab fragments from IgG. Table 2 states that at pH5 Type 11 do not bind the Fc fragment, while at pH5 Type 11 does bind Fab fragment. Therefore, Fahnestock et

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al., teach a nucleic acid molecule as claimed since the ability of the Fc fragment is determined by chromatography conditions.

Furthermore, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

It is noted that applicants' argument that the instantly claimed nucleic acid molecules is more effective at binding than the nucleic acid molecules is therefore, not persuasive, since the instant claims do not become patentable simply because they

have been described as somewhat superior to some other product for the same use. Therefore applicants' arguments are not persuasive and the rejection is maintained.

### ***Claim Objections***

7. Claims 33-38 are objected to because they depend from rejected claim 32. However, the claims would be allowable if rewritten to overcome the rejection(s) set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines



June 18, 2006

  
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